

112TH CONGRESS  
1ST SESSION

# H. R. 2123

To amend the Public Health Service Act to improve the diagnosis and treatment of hereditary hemorrhagic telangiectasia, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 3, 2011

Mr. GALLEGLY (for himself, Mr. WU, and Mr. HIMES) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend the Public Health Service Act to improve the diagnosis and treatment of hereditary hemorrhagic telangiectasia, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

### 3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Hereditary Hemor-  
5 rhagic Telangiectasia Diagnosis and Treatment Act of  
6 2011”.

### 7 **SEC. 2. FINDINGS.**

8 The Congress finds as follows:

1           (1) Hereditary hemorrhagic telangiectasia  
2           (“HHT”) is a largely undiagnosed or misdiagnosed  
3           vascular genetic bleeding disorder that causes abnor-  
4           malities of the blood vessels. A person with HHT  
5           has the tendency to form blood vessels that lack the  
6           capillaries between an artery and vein. HHT can  
7           cause spontaneous hemorrhage or stroke when brain  
8           or lung arteriovenous malformations, which are tan-  
9           gled blood vessels, rupture unexpectedly, in all age  
10          groups. In addition to hemorrhagic stroke, embolic  
11          stroke and brain abscess occur in approximately  
12          30% of persons with HHT caused by artery-vein  
13          malformations in the lung (due to lack of capillaries  
14          between the arterial and venous systems which nor-  
15          mally filter out clots and bacteria), causing disability  
16          and sudden premature death.

17          (2) One in 5,000 American children and adults  
18          suffer from HHT.

19          (3) Studies have found an increase in morbidity  
20          and mortality rates for individuals who suffer from  
21          HHT.

22          (4) Due to the widespread lack of knowledge,  
23          accurate diagnosis, and appropriate intervention, 90  
24          percent of HHT-affected families are at risk for pre-

1       ventable life-threatening and disabling medical inci-  
2       dents such as stroke.

3           (5) Early detection, screening, and treatment  
4       can prevent premature deaths, spontaneous hemor-  
5       rhage, hemorrhagic stroke, embolic stroke, brain ab-  
6       scess, and other long-term health care complications  
7       resulting from HHT.

8           (6) HHT is an important health condition with  
9       serious health consequences which are amenable to  
10      early identification and diagnosis with suitable tests,  
11      and acceptable and available treatments in estab-  
12      lished treatment centers.

13          (7) Timely identification and management of  
14      HHT cases is an important public health objective  
15      because it will save lives, prevent disability, and re-  
16      duce direct and indirect health care costs expendi-  
17      tures.

18          (8) Without a new program for early detection,  
19      screening, and treatment, 14,000 children and  
20      adults who suffer from HHT in the population today  
21      will suffer premature death and disability.

22   **SEC. 3. PURPOSE.**

23       The purpose of this Act is to create a federally led  
24      and financed initiative for early diagnosis and appropriate  
25      treatment of hereditary hemorrhagic telangiectasia that

1 will result in the reduction of the suffering of families,  
2 prevent premature death and disability, and lower health  
3 care costs through proven treatment interventions.

4 **SEC. 4. NATIONAL INSTITUTES OF HEALTH.**

5 Part B of title IV of the Public Health Service Act  
6 (42 U.S.C. 284 et seq.) is amended by adding at the end  
7 the following:

8 **“SEC. 409K. HEREDITARY HEMORRHAGIC TELANGIECTASIA.**

9 “(a) HHT INITIATIVE.—

10 “(1) ESTABLISHMENT.—The Secretary shall es-  
11 tablish and implement an HHT initiative to assist in  
12 coordinating activities to improve early detection,  
13 screening, and treatment of people who suffer from  
14 HHT. Such initiative shall focus on—

15 “(A) advancing research on the causes, di-  
16 agnosis, and treatment of HHT, including  
17 through the conduct or support of such re-  
18 search; and

19 “(B) increasing physician and public  
20 awareness of HHT.

21 “(2) CONSULTATION.—In carrying out this sub-  
22 section, the Secretary shall consult with the Director  
23 of the National Institutes of Health and the Director  
24 of the Centers for Disease Control and Prevention.

25 “(b) HHT COORDINATING COMMITTEE.—

1           “(1) ESTABLISHMENT.—Not later than 60 days  
2           after the date of the enactment of this section, the  
3           Secretary, in consultation with the Director of the  
4           National Institutes of Health, shall establish a com-  
5           mittee to be known as the HHT Coordinating Com-  
6           mittee.

7           “(2) MEMBERSHIP.—

8                   “(A) IN GENERAL.—The members of the  
9                   Committee shall be appointed by the Secretary,  
10                  in consultation with the Director of the Na-  
11                  tional Institutes of Health, and shall consist of  
12                  12 individuals who are experts in HHT or  
13                  arteriovenous malformation (AVM) as follows:

14                          “(i) Four representatives of HHT  
15                          Treatment Centers of Excellence des-  
16                          ignated under section 317U(c)(1).

17                          “(ii) Four experts in vascular, molec-  
18                          ular, or basic science.

19                          “(iii) Four representatives of the Na-  
20                          tional Institutes of Health.

21           “(B) CHAIR.—The Secretary shall des-  
22           ignate the Chair of the Committee from among  
23           its members.

24           “(C) INTERIM MEMBERS.—In place of the  
25           4 members otherwise required to be appointed

1 under paragraph (2)(A)(i), the Secretary may  
2 appoint 4 experts in vascular, molecular, or  
3 basic science to serve as members of the Com-  
4 mittee during the period preceding designation  
5 and establishment of HHT Treatment Centers  
6 of Excellence under section 317U.

7 “(D) PUBLICATION OF NAMES.—Not later  
8 than 30 days after the establishment of the  
9 Committee, the Secretary shall publish the  
10 names of the Chair and members of the Com-  
11 mittee on the Website of the Department of  
12 Health and Human Services.

13 “(E) TERMS.—The members of the Com-  
14 mittee shall each be appointed for a 3-year term  
15 and, at the end of each such term, may be re-  
16 appointed.

17 “(F) VACANCIES.—A vacancy on the Com-  
18 mittee shall be filled by the Secretary in the  
19 same manner in which the original appointment  
20 was made.

21 “(3) RESPONSIBILITIES.—The Committee shall  
22 develop and coordinate implementation of a plan to  
23 advance research and understanding of HHT by—

24 “(A) conducting or supporting basic,  
25 translational, and clinical research on HHT

1 across the relevant national research institutes,  
2 national centers, and offices of the National In-  
3 stitutes of Health, including the National  
4 Heart, Lung, and Blood Institute; the National  
5 Institute of Neurological Disorders and Stroke;  
6 the National Institutes of Diabetes and Diges-  
7 tive and Kidney Diseases; the Eunice Kennedy  
8 Shriver National Institute of Child Health and  
9 Human Development; the National Cancer In-  
10 stitute; and the Office of Rare Diseases; and

11 “(B) conducting evaluations and making  
12 recommendations to the Secretary, the Director  
13 of the National Institutes of Health, and the  
14 Director of the National Cancer Institute re-  
15 garding the prioritization and award of Na-  
16 tional Institutes of Health research grants re-  
17 lating to HHT, including with respect to grants  
18 for—

19 “(i) expand understanding of HHT  
20 through basic, translational, and clinical  
21 research on the cause, diagnosis, preven-  
22 tion, control, and treatment of HHT;

23 “(ii) training programs on HHT for  
24 scientists and health professionals; and

1 “(iii) HHT genetic testing research to  
2 improve the accuracy of genetic testing.

3 “(c) DEFINITIONS.—In this section:

4 “(1) The term ‘Committee’ means the HHT  
5 Coordinating Committee established under sub-  
6 section (b).

7 “(2) The term ‘HHT’ means hereditary hemor-  
8 rhagic telangiectasia.”.

9 **SEC. 5. CENTERS FOR DISEASE CONTROL AND PREVEN-**  
10 **TION.**

11 Part B of title III of the Public Health Service Act  
12 is amended by inserting after section 317T (42 U.S.C.  
13 247b–22) the following:

14 **“SEC. 317U. HEREDITARY HEMORRHAGIC**  
15 **TELANGIECTASIA.**

16 “(a) IN GENERAL.—With respect to hereditary hem-  
17 orrhagic telangiectasia (in this section referred to as  
18 ‘HHT’), the Director of the Centers for Disease Control  
19 and Prevention (in this section referred to as the ‘Direc-  
20 tor’) shall carry out the following activities:

21 “(1) The conduct of population screening de-  
22 scribed in subsection (c).

23 “(2) The identification and conduct of inves-  
24 tigations to further develop and support guidelines



1 for diagnosis of, and intervention for, HHT, includ-  
2 ing cost-benefit studies.

3 “(3) The development of a standardized survey  
4 and screening tool on family history.

5 “(4) The establishment, in collaboration with a  
6 voluntary health organization representing HHT  
7 families, of an HHT resource center within the Cen-  
8 ters for Disease Control and Prevention to provide  
9 comprehensive education on, and disseminate infor-  
10 mation about, HHT to health professionals, pa-  
11 tients, industry, and the public.

12 “(5) The conduct or support of public aware-  
13 ness programs in collaboration with medical, genetic,  
14 and professional organizations to improve the edu-  
15 cation of health professionals about HHT.

16 “(b) COLLABORATIVE APPROACHES.—The Director  
17 shall carry out this section through collaborative ap-  
18 proaches within the National Center on Birth Defects and  
19 Developmental Disabilities and the Division for Heart Dis-  
20 ease and Stroke Prevention of the Centers for Disease  
21 Control and Prevention.

22 “(c) POPULATION SCREENING.—In carrying out pop-  
23 ulation screening under subsection (a)(1), the Director  
24 shall—

1           “(1) designate and provide funding for a suffi-  
2           cient number of HHT Treatment Centers of Excel-  
3           lence to improve patient access to information, treat-  
4           ment, and care by HHT experts;

5           “(2) conduct surveillance by means of a re-  
6           gional population study, supplemented by sentinel  
7           health care provider or center surveillance, and by  
8           administrative database analyses as useful, to accu-  
9           rately identify—

10                   “(A) the prevalence of HHT; and

11                   “(B) the prevalence of hemorrhagic and  
12                   embolic stroke, and brain abscess, resulting  
13                   from HHT;

14           “(3) include HHT screening questions in the  
15           Behavioral Risk Factor Surveillance System survey  
16           conducted by the Centers for Disease Control and  
17           Prevention in order to screen a broader population  
18           and more accurately determine the prevalence of  
19           HHT;

20           “(4) provide data collected under paragraph  
21           (2)(B) to the Paul Coverdell National Acute Stroke  
22           Registry to facilitate—

23                   “(A) analyses of the natural history of  
24                   hemorrhagic and embolic stroke in HHT; and

1           “(B) development of screening and artery-  
2           vein malformation treatment guidelines specific  
3           to prevention of complications from HHT;

4           “(5) develop and implement programs, targeted  
5           for physicians and health care professional groups  
6           likely to be accessed by families with HHT, to in-  
7           crease HHT diagnosis and treatment rates through  
8           the—

9           “(A) establishment of a partnership with  
10          HHT Treatment Centers of Excellence des-  
11          ignated under paragraph (1) through the cre-  
12          ation of an international database of patients  
13          assessed at such HHT Treatment Centers of  
14          Excellence (including with respect to phenotype  
15          information, genotype information, transfusion  
16          dependence, and radiological findings);

17          “(B) integration of such database with—

18                 “(i) the universal data collection sys-  
19                 tem used by the Centers for monitoring he-  
20                 mophilia with the blood disorders; and

21                 “(ii) the Paul Coverdell National  
22                 Acute Stroke Registry; and

23          “(C) inclusion of other medical providers  
24          who treat HHT patients; and

1           “(6) use existing administrative databases on  
2       non-HHT Treatment Center of Excellence pa-  
3       tients—

4           “(A) to learn about the natural history of  
5       HHT and the efficacy of various treatment mo-  
6       dalities; and

7           “(B) to better inform and develop screen-  
8       ing and treatment guidelines associated with  
9       improvement in health care outcomes, and re-  
10      search priorities relevant to HHT.

11      “(d) ELIGIBILITY FOR DESIGNATION AS HHT  
12      TREATMENT CENTER OF EXCELLENCE.—In carrying out  
13      subsection (c)(1), the Director may designate as an HHT  
14      Treatment Center of Excellence only academic health cen-  
15      ters demonstrating each of the following:

16           “(1) The academic health center possesses a  
17      team of medical experts capable of providing com-  
18      prehensive evaluation, treatment, and education to  
19      individuals with known or suspected HHT and their  
20      health care providers.

21           “(2) The academic health center has sufficient  
22      personnel with knowledge about HHT, or formal col-  
23      laboration with one or more partnering organizations  
24      for personnel or resources, to be able to—

1           “(A) respond in a coordinated, multidisci-  
2           plinary way to patient inquiries; and

3           “(B) coordinate evaluation, treatment, and  
4           education of patients and their families in a  
5           timely manner.

6           “(3) The academic health center has the fol-  
7           lowing personnel, facilities, and patient volume:

8           “(A) A medical director with—

9                   “(i) specialized knowledge of the main  
10                  organ manifestations of HHT; and

11                  “(ii) the ability to coordinate the mul-  
12                  tidisciplinary diagnosis and treatment of  
13                  patients referred to the center.

14           “(B) Administrative staff with—

15                   “(i) sufficient knowledge to respond to  
16                  patient inquiries and coordinate patient  
17                  care in a timely fashion; and

18                   “(ii) adequate financial support to  
19                  allow the staff to commit at least 25 to 50  
20                  of their time on the job to HHT.

21           “(C) An otolaryngologist with experience  
22           and expertise in the treatment of recurrent epi-  
23           staxis in HHT patients.

1           “(D) An interventional radiologist with ex-  
2           perience and expertise in the treatment of pul-  
3           monary arteriovenous malformations (AVM).

4           “(E) A genetic counselor or geneticist with  
5           the expertise to provide HHT-specific genetic  
6           counseling to patients and families.

7           “(F) On-site facilities to screen for all  
8           major organ manifestations of HHT.

9           “(G) A patient volume of at least 25 new  
10          HHT patients per year.

11          “(H) Established mechanisms to coordi-  
12          nate surveillance and outreach with HHT pa-  
13          tient advocacy organizations.”.

14   **SEC. 6. ADDITIONAL HEALTH AND HUMAN SERVICES AC-**  
15                   **TIVITIES.**

16          With respect to hereditary hemorrhagic telangiectasia  
17          (in this section referred to as “HHT”), the Secretary of  
18          Health and Human Services, acting through the Adminis-  
19          trator of the Centers for Medicare & Medicaid Services,  
20          shall award grants on a competitive basis—

21               (1) for an analysis by grantees of the Medicare  
22          Provider Analysis and Review (MEDPAR) file to de-  
23          velop preliminary estimates on the total costs to the  
24          Medicare program under title XVIII of the Social  
25          Security Act for items, services, and treatments for

1       HHT furnished to individuals with HHT who are  
2       entitled to benefits under part A of title XVIII of  
3       the Social Security Act or enrolled under part B of  
4       such title; and

5               (2) to make recommendations regarding an en-  
6       hanced data collection protocol to permit a more  
7       precise determination of the total costs described in  
8       paragraph (1).

9       **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

10       (a) IN GENERAL.—To carry out section 409K of the  
11       Public Health Service Act as added by section 4 of this  
12       Act, section 317U of the Public Health Service Act as  
13       added by section 5 of this Act, and section 6 of this Act,  
14       there is authorized to be appropriated \$5,000,000 for each  
15       of fiscal years 2012 through 2016.

16       (b) RESOURCE CENTER.—Of the amount authorized  
17       to be appropriated under subsection (a) for each of fiscal  
18       years 2012 through 2016, \$1,000,000 shall be for car-  
19       rying out section 317U(a)(4) of the Public Health Service  
20       Act, as added by section 5 of this Act.

21       (c) OFFSET.—There is authorized to be appropriated  
22       to the Department of Health and Human Services for sal-  
23       aries and expenses of the Department for each of fiscal  
24       years 2012 through 2016 the amount that is \$5,000,000

- 1 less than the amount appropriated for such salaries and
- 2 expenses for fiscal year 2011.

